

REMARKS/ARGUMENTS

Rejections under 35 USC 112, second paragraph

Claims 11 and 28 are rejected under 35 USC 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claims 11 and 28 are rejected for citing the term “optionally.” Applicant has amended these claims to remove this term. Applicant respectfully submits that claims 11 and 28, as currently amended, overcome the present rejection.

Claims 13, 14, 30 and 31 are rejected for insufficient antecedent basis. Applicant accordingly has revised the claims to introduce the term “the coding” for proper antecedent basis. Applicant respectfully submits that claims 13, 14, 30 and 31, as currently amended, overcome the present rejection.

Rejections under 35 USC 103(a)

Claims 1, 3, 5, 10, 12, 15, 18, 20, 22, 27, 29, and 32 have been rejected 35 USC 103(a) as being unpatentable over US Patent No. 4,531,521 to Haverstock (“Haverstock”) in view of U.S. Patent No. 2,762,371 to Guio (“Guio”). Applicant respectfully traverses this rejection. The proposed combination of references fails to teach or suggest the limitations of independent claims 1 and 18. In particular, the instant office action states the following language on pages 3 to 4:

(claim 1) Fig. 6 of Haverstock discloses a two-component device for closing a laceration or incision, comprising:...the attachment of the one or more first and second connecting members to the first and second adhesive-backed anchoring members form attached and bridging portions of the one or more first and second connecting members such that the attached portions are attached to the first and second adhesive-backed anchoring members, and the bridging portions span over the laceration area between the first and second adhesive-backed anchoring members (col. 7, ll. 50-68), wherein the adhesive is applied to at least a portion of a lower surface of the first and second connecting members (see cross-section shown in Fig. 7). Haverstock is silent with regards to the bridging portions being substantially free of adhesive.

Applicant notes that Haverstock fails to teach or suggest every element of the present invention, and in addition to connecting members lacking a portion substantially free of adhesive, other substantial, non-obvious distinctions exist between the present invention and the Haverstock device. In particular, Applicant notes that the device of Haverstock fails to teach a bridging portion spanning over a laceration area, and Haverstock also fails to teach one or

more connecting members extending from one edge of a first component in a first direction and one or more connecting members extending from one edge of a second component in a second direction generally opposite the first direction.

First, Haverstock fails to teach connecting members extending from an edge of each component and forming a bridging portion having a lower surface substantially free of adhesive. Instead, Haverstock teaches folded over portions adhered to the connecting members for later use and completely covered in adhesive for later attachment to the opposite connecting member. For example, language at column 4, lines 25 through 44, reproduced here in pertinent part, describes this configuration of the Haverstock device:

The sheet portion 12 has an integral folded back flap portion 24 which is of the same material and construction as sheet portion 12, but is laid back against the upper or non-skin engaging surface of sheet portion 12 in position for later use in closing the separated skin portions as will be explained. The sheet portion 24 is temporarily adhesively or otherwise affixed to the upper surface of the sheet portion 12, such as by use of a small amount of adhesive...The important thing is to keep the portions 12 and 24 attached so that the portion 24 is out of the way until it is needed to close the skin separation. The upper surface of sheet portion 14, and/or the folded back upper surface of the sheet portion 24 are covered or coated with other layers of adhesive material such as layers 28 and 29 as shown in FIG. 2...

The folded back portions of the cited embodiment 50 function similarly, as described at column 7, lines 50-68, reproduced here in pertinent part:

FIG. 6 shows another embodiment 50 of the subject construction which similar in many respects to the embodiment 10 including having two adjacent, connected sheet members 52 and 54, each of which has spaced folded back sheet portions 58 and 60, and 62 and 64 respectively.

The folded back sheet portions are non-analogous to applicant's connecting members which extend from an edge of each of the two components. The configuration of the present invention enables proper application such that the connecting members align properly with each other. Because the folded back sheet portions of the Havertock device remain adhered to the sheet members and "out of the way" until "needed to close the skin separation," Haverstock fails to teach or suggest the facile, accurate application provided by Applicant's device. For example, language at column 8, lines 69 through 49 instructs that careful alignment is necessary:

However, if the device is to be attached to close an existing skin separation then care may be required to make sure that the overlapping portions 58-64 are staggered as indicated.

Because the folded back sheet portions remain folded back during application of the sheet members, a user must properly sight accurate alignment of the two sheet members so that the folded back sheet portions on each sheet member will properly align with the folded back sheet portions on the opposite sheet member. This creates an opportunity for increased wound trauma if the sheet members require removal and repositioning to properly align initially misaligned folded back sheet portions.

In addition to lacking connecting members which extend from first and second components, the Haverstock device also lacks connecting members having bridging portions spanning over the laceration area. No gap exists in the Haverstock device over the laceration area. In every embodiment of the device as describe, Haverstock teaches abutting the components adhered to each side of a wound, thereby precluding any distance between components that would be spanned by a bridging portion. Colum 5, lines 29-49, reproduced her in pertinent part for convenience, further describe the functionality of the Haverstock device:

The sheet portion 12 is then ***aligned with the edge of the skin separation*** or with where the incision is to be made. Next, the sheet portion 12 is adhered to the skin using the adhesive layer 16. Similarly,...the edge of sheet portion 14 is aligned with the opposite side edge of the skin separation or incision in a position to be ***adjacent the edge of the folded back sheet portion 24*** when the skin separation is closed. Once aligned, the sheet portion 14 is also adhered to the skin...Folded back sheet portion 24 is then detached from sheet portion 12 by pulling up on it and thereafter it is pulled and if necessary stretched over and towards the opposite or far edge of the sheet portion 12 as shown in FIG. 5. ***This enables the edges of the portions 12 and 14 as well as the edges of the skin separation to be brought into abutment...***[Emphasis Added]

The Haverstock device requires aligning the portions 12 and 14 with the edges of the skin separation such that the edges of those portions will abut. This precludes any spanned area between the two portions adhered to either side of the incision. The embodiment of the Haverstock device referenced in the instant Office Action is described at Column 8, lines 13 to 21 as functioning exactly like the other embodiments:

The operation of the modified construction 50 is substantially similar to the operation of the constructions described above. For example, it can be attached to dry skin prior to surgery in which case the surgery will take place between the members 52 and 54 or it can be attached along a wet skin separation as in the case of field use to close a separation. In either case, the operation will be substantially the same...

FIGS. 6 and 7 of Haverstock also detail the abutment of members 52 and 54 and lack of a span over which a bridging portion would exist.

In contrast, the Applicant's device includes a bridging portion of each connecting member that spans between the first and second component. In addition to providing a view of the wound, this span allows for drainage of exudates and application of medicines. The device of Haverstock allows for no such visibility or accessibility to the wound during healing. In fact, at column 8, lines 30-34, Haverstock teaches reopening the device to inspect the wound and make readjustments if necessary:

It is further anticipated that if a proper selection of adhesive is made then the adhesive connections along the separation can be reopened as desired to inspect the injury or to draw the members closer together or to make some other adjustment as required.

Haverstock thus fails to teach a device having bridging portions spanning over the laceration area and instead teaches away from such a bridging portion by requiring separation of the components in order to inspect the injury.

Guio fails to cure the deficiencies of Haverstock. First, Applicant notes that Guio also fails to teach every element of the present invention. Applicant teaches a first component having connecting members extending from an edge thereof in a first direction and a second separate and distinct component comprising connecting members extending from an edge thereof in a second direction generally opposite the first direction. The connecting members comprise attached portions for attaching to the opposite component and bridging portions for spanning over the laceration area. In contrast, Guio fails to teach analogous elements. One skilled in the art would not look to Guio to cure the deficiency of Haverstock.

Guio is directed to a key-hole design bandage. Fig. 4 of Guio shows a first bandage 8 having an opening 16 and end portions 12 and 14, and a second bandage 10 comprising a central portion 26 with opposite and opposed semi-circular notches 28 therein and end portions 22 and 24. In use, end 22 of the second bandage 10 is inserted from underneath and into the opening 16 of the first bandage 8, such that the end 22 overlaps the top portion of end 12 of the first bandage 8. However, the semi-circle notch 28 of the second bandage 10 completely fills the opening 16 of the first bandage 8, leaving no spacing to provide for a fine adjustment of the unattached end 24 of the second bandage 10 relative to the attached end 12 of first bandage 8 when administering the bandage. Guio's device thus lacks lateral adjustability prior to adhering the ends of the device.

The noted element that the cited Guio reference fails to disclose is an essential, non-obvious element. The fact that Applicant's device is secured in place by the attachment of connecting members to flat flexible components offers a significant advantage relative to the cited prior art device. More specifically, Applicant's connecting members enable a degree of lateral adjustability during the application process that the Guio device fails to teach or suggest. Furthermore, the fact that Applicant's connecting members attach directly to the first and second components effectively reduces the range of freedom for lateral movement of the two wound edges relative to one another. To restate, Applicant teaches a bandage in which a first component wound edge is limited in the degree in which it can move generally laterally relative to a second component wound edge by being effectively tethered closely together by one or more connecting members. This increases stability of the presenting invention during healing.

Applicant thus respectfully submits that the proposed combination of references fails to teach or suggest the present invention as claimed in independent claims 1 and 18 and that those claims are in condition for allowance. Because claims 5, 10, 12, 15, 20, 22, 27, 29, and 32 depend from those independent claims, those dependent claims are also in condition for allowance. Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claims 4, 6-9, 16, 17, 21, 23-26, 33 and 34 are rejected under 35 USC 103(a) as being unpatentable over Haverstock in view of Guio and in further view of US 6,329,546 to Lebner (Lebner '564). Applicant respectfully traverses this rejection. Lebner '564 fails to cure the deficiency of the proposed combination of references. Namely, Lebner '564 fails to teach or suggest a bridging portion spanning over a laceration with no adhesive on the lower surface. At columns 1-2, lines 66-2, Lebner '564 describes this unrestricted adhesive application:

The means for attaching the first elongated connectors to the second flat flexible component, and the second elongated connectors to the first flat flexible component, are also, in preferred embodiments, adhesives.

Lebner '564 teaches away from connecting members having non-adhesive bridging portions and instead teaches strap like connectors with cut outs in the bridging portions. Language at column 4, lines 29-34 describes these connectors:

As mentioned above, preferred embodiment of the present invention include die cut embodiments. In such embodiment, the elongated connectors may be viewed as strap-like in their dimensions. In preferred embodiments, a portion of

the elongated connectors is cut away to increase the unobstructed surface area over the wound or incision.

Lebner '564 is thus directed toward teaching increased exposure to the incision site by removing material and thus provides no motivation for a bridging portion having no adhesive thereon. Instead, Lebner '564 teaches applying adhesive to the elongated connectors without restriction and removing a substantial portion of the bridging portion altogether.

Applicant respectfully submits that the proposed combination of references fails to teach or suggest Applicant's independent claims 1 and 18. Because claims 4, 6-9, and 17 depend from independent claim 1 and because claims 21, 23-26, 33 and 34 depend from independent claim 18, Applicant also submits that those claims are in condition for allowance. Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Claims 11, 13, 14, 28, 30 and 31 are rejected under 35 USC 103(a) as being unpatentable over Haverstock in view of Guio and in further view of US 6,043,406 to Sessions et al. ("Sessions et al."). Applicant respectfully traverses this rejection. Sessions et al. fails to cure the deficiency of the proposed combination of references. Namely, Sessions et al. fails to teach or suggest a two-component device having a bridging portion spanning over a laceration with no adhesive on the lower surface. Sessions et al. teaches a non-analogous unitary thin-film wound dressing. For example, column 4, lines 19 through 23 describe this unitary configuration:

Once cast on the cover sheet 16, **the unitary cover sheet 16** and thin urethane film 14 may be used in subsequent manufacturing steps without stretching, tearing, or otherwise destroying the thin urethane 14. [Emphasis Added]

The two –component device of Applicant's invention comprises a first and a second component which are separate and distinct from one another. Each component applies individually to either side of the wound or incision requiring closure, and the plurality of elongated connectors enable fine adjustments along the wound to close a wound of varying widths. Applicant's two-component device offers numerous advantages over the non-component device of Sessions et al. First, the use of two independently-positioned components enables a user to precisely align distinct wound edges on either side of the wound or incision to be closed. Unlike the non-component device of Sessions et al., Applicant's two-component device provides clear visibility of the wound, and access to the wound during the closure process. Thus, the wound can be cleaned during and after the closure process, and dressings

such as bacitracin may be applied. Furthermore, Applicant's design eliminates the potential problem of adhesive from the bandage contacting the wound area.

One skilled in the art would not look to the unitary wound dressing of Sessions et al. to teach or suggest any limitations of Applicant's two-component device. Sessions et al. thus fails to cure the deficiency of the proposed combination of references.

Applicant respectfully submits that the proposed combination of references fails to teach or suggest Applicant's independent claims 1 and 18. Because claims 11, 13, and 14 depend from independent claim 1 and because claims 28, 30 and 31 depend from independent claim 18, Applicant also submits that those claims are in condition for allowance. Applicant respectfully requests reconsideration and withdrawal of the present rejection.

Double Patenting Rejection

Claims 18 and 20-34 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/626785 and in view of Guio. While Applicant believes the claims of the subject application to be patentably distinct over those in the cited co-pending application, Applicant is prepared to file an executed terminal disclaimer in order to expedite prosecution should other issues of patentability be favorably resolved.

Claims 1, 3-18 and 20-34 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/626783 and in view of Guio. While Applicant believes the claims of the subject application to be patentably distinct over those in the cited co-pending application, Applicant is prepared to file an executed terminal disclaimer in order to expedite prosecution should other issues of patentability be favorably resolved.

Claims 1, 3-18 and 20-34 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/626040 and in view of Guio. While Applicant believes the claims of the subject application to be patentably distinct over those in the cited co-pending application, Applicant is prepared to file an executed terminal disclaimer in order to expedite prosecution should other issues of patentability be favorably resolved.

Claims 1, 3-18 and 20-34 have been provisionally rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over copending Application No. 10/625936 and in view of Guio. While Applicant believes the claims of the subject application to be patentably distinct over those in the cited co-pending application,

Applicant is prepared to file an executed terminal disclaimer in order to expedite prosecution should other issues of patentability be favorably resolved.

Summary

In light of the above, Applicant respectfully requests consideration of the subject patent application. Any deficiency or overpayment should be charged or credited to Deposit Account No. 50-4514.

Respectfully submitted,



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